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| APPLICATION NO.           | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------|-------------|----------------------|---------------------|------------------|
| 10/777,683                | 02/13/2004  | Richard B. Moss      | Q74236              | 5880             |
| 65565                     | 7590        | 10/16/2007           | EXAMINER            |                  |
| SUGHRUE-265550            |             |                      | FOSTER, CHRISTINE E |                  |
| 2100 PENNSYLVANIA AVE. NW |             |                      | ART UNIT            |                  |
| WASHINGTON, DC 20037-3213 |             |                      | PAPER NUMBER        |                  |
|                           |             |                      | 1641                |                  |
|                           |             |                      | MAIL DATE           |                  |
|                           |             |                      | DELIVERY MODE       |                  |
|                           |             |                      | 10/16/2007          |                  |
|                           |             |                      | PAPER               |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|   |                        |                     |
|---|------------------------|---------------------|
| <b>Advisory Action<br/>Before the Filing of an Appeal Brief</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|   | 10/777,683             | MOSS ET AL.         |
|   | <b>Examiner</b>        | <b>Art Unit</b>     |
|   | Christine Foster       | 1641                |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 October 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1.  The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a)  The period for reply expires 3 months from the mailing date of the final rejection.  
 b)  The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2.  The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3.  The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a)  They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b)  They raise the issue of new matter (see NOTE below);  
 (c)  They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d)  They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4.  The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5.  Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6.  Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7.  For purposes of appeal, the proposed amendment(s): a)  will not be entered, or b)  will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-16, 19 and 20.

Claim(s) withdrawn from consideration: 17 and 18.

#### AFFIDAVIT OR OTHER EVIDENCE

8.  The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9.  The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10.  The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11.  The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.
12.  Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_
13.  Other: \_\_\_\_\_.

LONG V. LE 10/18/07

SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

Continuation of 3. NOTE: The amendments raise new issues in that claim 1 now requires the step of "genotypically or phenotypically confirming the diagnosis or the determination of the presence or absence of risk or assessment of the level of the risk", which was not previously a limitation of the claims. This new confirmation step requires further consideration in light of the pending rejections under 112, 1st paragraph. This limitation also raises the issue of new matter because support could not be found for such a step where indicated by Applicant (see Remarks, page 8). Specifically, the specification passage to which Applicant points at page 2 is in the context of describing prior art methods and does not appear to provide support for genotypic or phenotypic confirmation steps in the context of Applicant's claimed invention. Claim 1 also now recites that the CAP 18 measurement indicates "possible" diagnosis or "possible" presence of risk, which was not previously a limitation of the claims and would require further consideration and/or search. The amendments also change the scope of one or more claims in that claim 1 now recites measuring "native" CAP 18, which was not previously a limitation of the claims.

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's arguments regarding the rejections of record are acknowledged but are moot because the amendment will not be entered for the reasons detailed above.